UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

David Robert Groves,

Civ. No. 15-3206 (PAM/BRT)

Plaintiff,

v.

MEMORANDUM AND ORDER

Secretary of Health and Human Services,

Defendant.

This matter is before the Court on the parties' cross-Motions for Summary Judgment. For the reasons that follow, Defendant's Motion is granted and Plaintiff's Motion is denied.

BACKGROUND

Plaintiff David Groves, proceeding in this matter pro se, contends that the Department of Health and Human Services breached its contract with him by refusing to pay for Cialis through his Medicare Part D prescription drug plan, MedicareBlue Rx.

In 2012, Groves was diagnosed with erectile dysfunction. (Admin. R. at 391-92.) His physician prescribed Cialis for daily use. (<u>Id.</u>) In 2013, Groves was also diagnosed with benign prostatic hyperplasia, or BPH. (<u>Id.</u> at 394.) His physician continued his Cialis prescription to treat both conditions, but in the certification to Medicare listed only his ED as the reason for the Cialis prescription. (<u>Id.</u> at 176 (citing diagnosis (ICD-9) code 607.84 or "impotence, organic origin" (http://www.icd9data.com/2013/Volume1/580-629/

600-608/607/607.84.htm, last visited June 27, 2016).) Medicare denied coverage for the Cialis. (Admin. R. at 209.) Groves sought a redetermination of this decision, and when that was unsuccessful (<u>id.</u> at 195-203), he asked for reconsideration, which was also unsuccessful. (<u>Id.</u> at 168.) Ultimately, Groves sought a hearing before an Administrative Law Judge.

The hearing took place in October 2014. (See id. at 380-403 (hearing transcript).) The ALJ asked Groves to provide additional information regarding his medical necessity for Cialis. In response, Groves submitted a statement reiterating that his clinic, the Park Nicollet Sexual Health Clinic, did not prescribe the formulary alternative drugs and that to receive any of these alternative drugs he would have to see a urologist. (Id. at 63.) The plan in turn noted that Groves's physician at Park Nicollet was only treating Groves's ED, and that its decision to deny coverage was therefore justified. (Id. at 60.) The ALJ determined that the plan was not required to cover Groves's Cialis prescription. (Id. at 40-45.)

Groves appealed this determination to the Medicare Appeals Council, which affirmed the decision in June 2015. (<u>Id.</u> at 4-14.) The MAC noted that Cialis was not on the plan's formulary even as a treatment for BPH and thus that Groves was required to try two alternative formulary medications before being allowed to take a non-formulary drug to treat his condition. (<u>Id.</u> at 12-13.) Because Groves had not done so, the MAC denied his appeal. This lawsuit followed.

The Complaint does not contain any causes of action. Rather, it demands that the

Court order the Department of Health and Human Services to add Cialis to its Medicare Part D coverage. In his Motion, Groves contends that the Evidence of Coverage for his prescription plan constitutes a contract, which the plan breached by failing to "follow the treatment plans that you and your doctors agree upon."

DISCUSSION

Summary judgment is proper if there are no disputed issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). The Court must view the evidence and inferences that may be reasonably drawn from the evidence in the light most favorable to the nonmoving party. Enter. Bank v. Magna Bank, 92 F.3d 743, 747 (8th Cir. 1996).

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986); Enter. Bank, 92 F.3d at 747. A party opposing a properly supported motion for summary judgment may not rest on mere allegations or denials, but must set forth specific facts in the record showing that there is a genuine issue for trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). In cases such as this, the Secretary's final decision, in the form of the MAC determination, is entitled to deference if supported by substantial evidence in the record. Smith v. Heckler, 735 F.2d 312, 315 (8th Cir. 1983).

Federal law prohibits Medicare from covering drugs used exclusively to treat erectile dysfunction. 42 U.S.C. § 1395w-102(e)(2)(A). A drug used to treat both ED and

BPH might be covered, but in this instance, Groves's Medicare prescription plan did not include Cialis in its list of covered drugs, also known as its formulary. (Admin. R. at 221-286 (formulary).) The plan offered other drugs that could be used to treat both ED and BPH, but Groves does not want to take those drugs. He wants to take Cialis.

Medicare regulations allow Medicare Part D plans to determine what drugs are covered under their formularies. 42 C.F.R. § 423.120(b)(2). The regulations also specify how person can request coverage for a drug that is not included in his plan's formulary. Id. § 423.578(b). To do so, the person may provide a statement from his physician that the off-formulary drug is "medically necessary to treat the enrollee's disease or medical condition because . . . [a]ll of the covered [] drugs . . . for treatment of the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse side effects for the enrollee, or both." Id. § 423.578(b)(5)(i). In the alternative, the physician's statement may aver that the formulary's alternative drugs have "been ineffective in the treatment of the enrollee's disease or medical condition or . . . [are] likely to be ineffective or adversely affect the drug's effectiveness . . . or [have] caused or . . . [are] likely to cause an adverse reaction or harm to the enrollee." Id. § 423.578(b)(5)(ii).

To treat BPH, Groves's plan's formulary lists five different drugs. Groves alleges that he tried one of these drugs, Flomax, and was dissatisfied with it. He did not try any others. The plan, however, requires that its participants attempt at least two formulary drugs before seeking permission for an off-formulary drug, unless the participant has a documented intolerance, contraindication, or hypersensitivity to the drug. (Admin. R. at

195.) But the information from Groves's physician indicated that Groves had not tried any of the five other drugs, and also stated that Groves's medical history did not preclude treatment with the other drugs included in the formulary to treat BPH. (Id. at 176, 180.) Thus, substantial evidence supports the MAC's conclusion that no exception to the formulary was warranted in Groves's case.

Groves argues that his physician's determination that Cialis was the best medicine to treat both his ED and BPH should be controlling. In support of this, he points to the plan's requirement that Groves "follow the treatment plans that you and your doctors agree upon." (Id. at 349.) But this statement does not mean that the plan is obligated to cover whatever medication Groves's doctor prescribes. Nor does the statement constitute a contractual obligation on the part of the plan, and it was not a breach of any contract for the plan to decline to cover the specific medication that Groves's physician prescribed.

The regulations are clear that a plan participant may obtain an exception to a formulary medication only by showing that those medications are not appropriate for him. Groves failed to do so and the Secretary's decision must be upheld.

CONCLUSION

Accordingly, IT IS HEREBY ORDERED that:

1. Defendant's Motion for Summary Judgment (Docket No. 27) is **GRANTED**; and

2. Plaintiff's Motion for Summary Judgment (Docket No. 23) is **DENIED**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Dated: June 29, 2016

s/Paul A. Magnuson

Paul A. Magnuson United States District Court Judge